



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4824]

Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is opening a public docket to solicit input and comments from interested stakeholders, including racial and ethnic minority, underrepresented, and underserved populations in establishing strategic priorities for the Office of Minority Health and Health Equity (OMHHE). This will help the Agency ensure that important health concerns are carefully considered in establishing priorities.

DATES: Submit either electronic or written comments by February 28, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 28, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 28, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-N-4824 for "Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public

Docket; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine Merenda, Food and Drug Administration, Office of Minority Health and Health Equity, 10903 New Hampshire Ave., Bldg. 32, Rm. 2382, Silver Spring, MD 20993, 301-796-8453, Fax: 301-847-8601, email: Christine.merenda@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA's OMHHE serves to promote and protect the health of diverse populations through research and communication of science that addresses health disparities and health equity. Established in 2010, OMHHE provides leadership and policy direction for FDA regarding issues relating to the health of racial and ethnic minority, underrepresented, and underserved populations. OMHHE's stakeholders reflect the diversity of the U.S. population, including individuals of low socioeconomic status and historically underrepresented populations.

Currently OMHHE has program areas that focus on outreach and communication, as well as research and collaboration. The outreach and communication program strives to improve FDA communication with racial and ethnic minority populations and leads the Agency's Language Access program that provides consumers (including those with limited English proficiency) information that is easy to read, culturally competent, and available in multiple languages and formats. The research and collaboration program supports research projects that study health disparities that disproportionately affect racial and ethnic minority, underrepresented, and underserved populations, as well as projects that analyze data that can answer regulatory science questions. To aid data analysis, OMHHE issued a final guidance in

October 2016 entitled “Collection of Race and Ethnicity Data in Clinical Trials” (available at <https://www.fda.gov/media/75453/download>) to ensure that subpopulation data are collected consistently by industry.

OMHHE also works with academic institutions as part of the Centers of Excellence in Regulatory Science and Innovation, which are collaborations between FDA and academic institutions to advance regulatory science through innovative research, education, and scientific exchanges. In addition, OMHHE supports and collaborates with academic institutions and other stakeholders through the Broad Agency Announcement (available at <https://www.fda.gov/science-research/advancing-regulatory-science/regulatory-science-extramural-research-and-development-projects>) to spur innovation in the field of regulatory science.

OMHHE recognizes that more needs to be done to reach the goal of health equity and eliminating health disparities. Multiple complex factors can affect the health of racial and ethnic minority, underrepresented, and underserved populations, some of which are outside the purview of FDA, so it is important for OMHHE to develop a list of priorities to focus our efforts where FDA engagement can have the most impact.

FDA believes it is crucial to ask for input from the public, through *Federal Register* notices, public meetings, and workshops. OMHHE would like to have input from interested stakeholders including, racial and ethnic minority, underrepresented, and underserved populations in establishing strategic priorities for the office. This will help ensure that important health concerns are carefully considered in establishing priorities. Therefore, FDA is issuing this *Federal Register* notice to open a docket (FDA-2019-N-4824) for the public to submit comments

on priorities for FDA's OMHHE. FDA will take the suggestions and information submitted to the docket into consideration when developing the priorities for OMHHE.

## II. Request for Comments

FDA engagement can have a direct impact on advancing health equity in a number of areas, such as:

- Efforts that generate clinical evidence to improve generalizability of clinical trial findings and bridge the knowledge gap about the medical products' performance in racial and ethnic minority populations.
- Direct outreach to racial and ethnic minority, underrepresented, and underserved populations to promote access to relevant information on medical products to improve safety and efficacy.
- Coordination with other Federal Agencies and external stakeholders to support research on medical products that can address health disparities.
- Performing direct outreach to racial and ethnic minority, underrepresented, and underserved populations (e.g., raising awareness on inclusion of racial and ethnic minority populations in clinical trials).
- Leading the identification of regulatory decisions that can benefit from participation of racial and ethnic minority, underrepresented, and underserved populations.
- Generating research topics/interests and areas of focus that predominantly affect racial and ethnic minority populations.
- Identification of opportunities of collaboration to generate efforts to address research gaps that predominantly affect racial and ethnic minority populations.

We encourage interested stakeholders to submit comments on the areas and types of engagement FDA's OMHHE should prioritize in the coming year(s), and potential mechanisms that can be used to implement them (e.g. through collaborations and partnerships).

Dated: December 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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